

Application Serial No. 10/813,214
Reply to Office Action mailed January 17, 2008
Response dated April 15, 2008

In the Claims

Claims 1-49 (Cancelled)

50. (Previously Presented) An injector device assembly comprising:
- a sterile insertion set with a housing and a hollow cannula;
 - a device housing, said insertion set positioned removably from and within said device housing;
 - a plunger received within said device housing for movement between an advanced position and a retracted position, said cannula being transcutaneously placed upon movement of the plunger from the retracted position to the advanced position, said insertion set being separable from said plunger;
 - said device housing having a forward end defining a surface of placement against the skin of a patient; and
 - a cover member covering an opening defined in said forward end and removably connected to a portion of said device housing, said cover member and said device housing assuring sterile conditions of said insertion set within said device housing prior to removal of said cover member.
51. (Previously Presented) The injector device assembly of claim 50, said injector device including an insertion needle extending through said hollow cannula and being in frictional engagement with said hollow cannula.
52. (Previously Presented) The injector device assembly of claim 50, said insertion set being an infusion set, said insertion set housing including an adhesive layer for adhering said insertion set housing to the skin of a patient.
53. (Previously Presented) The injector device assembly of claim 50, said insertion set being a glucose sensor.

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54. (Previously Presented) The injector device assembly of claim 51, said insertion needle being secured to said plunger by a stable connection preventing loss of the insertion needle during use of the device.

55. (Previously Presented) The injector device of claim 54, said insertion needle being secured to said plunger by press-fit.

56. (Previously Presented) The injector device assembly of claim 50, including a trigger for releasably retaining said plunger in the retracted position, the trigger being operable to release the plunger for movement with a controlled force and speed toward the advanced position.

57. (Previously Presented) The injector device assembly of claim 51, said plunger including a support structure for reception and support of said insertion set, said support structure being removable from said insertion set while maintaining a transcutaneous placement of said insertion needle.

58. (Previously Presented) The injector device assembly of claim 50, indicia relating to the shelf life of said assembly being on said cover member.

59. (Previously Presented) The injector device assembly of claim 50, said plunger being in said advanced position prior to first time removal of said cover member.

60. (Previously Presented) An injector device assembly comprising:
a sterile insertion set having a housing and a hollow cannula;
a device housing;
a plunger slidably received within said device housing for movement between an advanced position and a retracted position, said cannula being transcutaneously placed upon movement of the plunger from the retracted position to the advanced position;
a spring for urging said plunger toward the advanced position;
said device housing having a forward end defining a surface for placement against the skin of a patient; and

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a releasable cover member covering said forward end, said cover member and said device housing assuring sterile conditions of said insertion set within said device housing prior to removal of said cover member;

wherein said spring comprises a number of individual, flexible plastics strips extending around a respective part of the periphery of the plunger, in a space between the plunger and the device housing, each strip being connected with the plunger and with the device housing.

61. (Previously Presented) The injector device assembly of claim 60, wherein said strips are integrally molded with said plunger and said device housing.

62. (Previously Presented) The injector device assembly of claim 60, each strip being essentially planar and non-deformed when the plunger is in the advanced position.

63. (Previously Presented) The injector device assembly of claim 62, two strips extending in a common plane around a respective part of said periphery of said plunger, and two further strips extending in a second plane around a respective part of said periphery, in said advanced position of said plunger.

64. (Previously Presented) The injector device assembly of claim 60, wherein said strips and said plunger are molded as a unitary component, said unitary component being connected to said device housing.

65. (Previously Presented) The injector device assembly of claim 51, wherein said removable cover is member includes a hollow for receiving a part of said insertion needle when said plunger is in said advanced position.

66. (Previously Presented) The injector device assembly of claim 50, said cover being repositionable subsequent to removal of said insertion set.

67. (Previously Presented) The injector device assembly of claim 56, said trigger releasing said plunger by manual deformation of said housing.

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68. (Previously Presented) The injector device assembly of claim 56, said insertion set including tubing for delivery of medication to said hollow cannula, said housing including an annular space for accommodating said tubing.

69. (Previously Presented) The injector device assembly of claim 50, said device housing including a releasable cover at a rearward end of said device housing.

70. (Previously Presented) The injector device of claim 69, said releasable cover at said rearward end being a membrane.

71. (Previously Presented) The injector device of claim 70, said releasable cover allowing through-flow of a sterilizing agent into said device housing with said insertion set.

72. (Previously Presented) An injector device assembly, comprising:

- a sterile insertion set with a housing and a hollow cannula, a molded device housing, said insertion set positioned within said device housing for delivery of said sterile insertion set to a patient;
- a molded plunger received within the device housing for movement between an advanced position and a retracted position;
- a lock for releasably locking said plunger in said retracted position, said housing being manually deformable to effect release of said plunger;
- a spring for urging the plunger from the retracted position towards the advanced position, said insertion set being separable from said plunger after placement of said cannula;
- said cannula being transcutaneously placed upon movement of the plunger from the retracted position to the advanced position;
- said housing having a forward end defining a surface for placement against the skin of a patient with the device housing in a predetermined orientation relative to the patient's skin; and
- a removable cover member covering an opening defined in said forward end and connected to a portion of said device housing;

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said cover member and said device housing assuring sterile conditions of said separable insertion set within said device housing prior to removal of said cover member.

73. (Currently Amended) The injector device assembly of claim 72 wherein the spring comprises a plurality of flexible plastic strips connected with the plunger and the housing ~~each flexible plastics member is formed as a strip, the device including at least two such strips, each strip extending around a respective part of the periphery of the plunger.~~

74. (Previously Presented) The injector device assembly of claim 73, wherein each of said strips is connected with the plunger and with the device housing, said connections being at different peripheral locations around the plunger.

75. (Currently Amended) The injector device assembly of claim 72 73, wherein each strip is essentially planar and non-deformed when the plunger is in the advanced position.

76. (Previously Presented) The injector device assembly of claim 73, wherein said strips and said plunger are molded as a unitary component, said unitary component being connected to said housing.

77. (Currently Amended) The injector device assembly of claim 72 73, wherein each of said flexible ~~members~~ extending strips extends in a space between the plunger and the device housing.

78. (Previously Presented) The injector device assembly of claim 72, wherein said insertion set is an infusion set.

79. (Previously Presented) The injector device assembly of claim 72, wherein said insertion set is a glucose sensor.

80. (Previously Presented) The injector device assembly according to claim 72, wherein said insertion set includes an insertion needle that is substantially non-detachably secured to said plunger.

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81. (Previously Presented) The injector device assembly of claim 80, wherein said insertion needle is hollow and has a lateral opening near said plunger.

82. (Previously Presented) The injector device assembly of claim 72, including manual engagement areas for the manual deformation of said housing to effect said release of said plunger.

83. (Previously Presented) The injector device assembly of claim 82, said manual engagement areas being diametrically opposed on said housing and being peripherally offset with respect to said lock.

84. (Previously Presented) The injector device assembly of claim 83 wherein said manual engagement areas are offset about 90°.

85. (Previously Presented) The injector device assembly of claim 83, said manual engagement areas being of fingertip size.

86. (Previously Presented) The injector device assembly of claim 72, said device housing including a releasable cover at a rearward end of said device housing.

87. (Previously Presented) The injector device of claim 86, said releasable cover at said rearward end being a membrane.

88. (Previously Presented) The injector device of claim 87, said releasable cover allowing through-flow of a sterilizing agent into said device housing with said insertion set.

89. (Previously Presented) The injector device assembly of claim 51, wherein said cover includes an upstanding cylinder for surrounding at least a portion of said insertion needle.

90. (Previously Presented) A method for making an injector device assembly comprising the steps of:

providing an injector device housing, said injector device housing having a movable plunger and providing an insertion set, said insertion set having an insertion set housing and a hollow cannula;

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placing said insertion set within said injector device housing;

connecting at least one releasable cover to at least a portion of said injector device housing to seal said insertion set within said injector device housing, said cover comprising a membrane; and

sterilizing said insertion set by flowing a sterilizing agent through said membrane into an interior of said injector device housing.

91. (Previously Presented) The method of claim 90, said device housing having a forward end defining a surface of placement against the skin of a patient with the device housing in a predetermined orientation relative to the patient's skin, said releasable cover member covering said forward end.

92. (Previously Presented) The method of claim 90, said device housing including a releasable cover at a rearward end of said housing.

93. (Currently Amended) An injector device for transcutaneously placing at least a portion of a cannula of a removable medical device through the skin of a patient, said injector device comprising:

a generally cylindrically shaped housing having a cavity formed therein, said housing including a forward end, said forward end defining a generally planar surface for placement against the skin of the patient;

a carrier member adapted for at least partial reception in said cavity, said carrier member comprising at least one piercing member substantially non-detachably secured to said carrier member;

a drive for urging movement of said carrier member relative to said housing, said drive extending at least partially around at least a portion of said carrier member; and

a releasable cover member covering said forward end, said cover member comprising an upstanding portion defining a bore;

wherein said at least one piercing member is adapted to receive said removable medical device.

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94. (Previously Presented) The injector device of claim 93, wherein said upstanding portion surrounds a portion of the needle.

95. (Previously Presented) The injector device of claim 93, wherein said upstanding portion is cylindrically shaped.

96. (Previously Presented) The injector device of claim 93, wherein said cover member and said housing are configured to provide sterile conditions for the medical device prior to removal of said cover member.

97. (Previously Presented) An injector device assembly comprising:
a sterile insertion set comprising a housing and a hollow cannula;
a device housing having a cavity formed therein, said insertion set positioned removably from and within said device housing;
a plunger having a piercing member connected to the plunger and positioned at least partially within said cavity, said piercing member extending at least partially through said cannula of said insertion set and said piercing member configured to move said insertion set toward the skin of a patient; and
a cover removably connected to a portion of said device housing, said cover accommodating a part of said piercing member, said cover and said device housing assuring sterile conditions of said insertion set within said device housing prior to removal of said cover.

98. (Previously Presented) The injector device assembly of claim 97, wherein said cover connects to and extends partially along a side wall at said forward portion of said device housing.

99. (Previously Presented) The injector device assembly of claim 97 wherein said cover is removably connected to said portion of said device housing by snap engagement.

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100. (Previously Presented) A method for providing an injector device assembly having a sterile insertion set provided within an injector device housing, the method comprising:

providing an injector device housing, said injector device housing having a movable plunger and a piercing member connected to the plunger;

providing an insertion set, said insertion set having an insertion set housing and a hollow cannula;

placing said insertion set within said injector device housing so that said piercing member extends at least partially through said cannula;

connecting at least one removable cover to a portion of said injector device housing to cover an opening defined in said injector device housing and to seal said insertion set within said injector device housing, the cover accommodating a part of said piercing member; and

sterilizing said insertion set within said injector device housing.